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APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.
08/477,316	06/07/95	GRAY	J 028723-060

EXAMINER
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18M2/0904

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ART UNIT	PAPER NUMBER
1807	5

DATE MAILED: 09/04/96

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

☒ Responsive to communication(s) filed on 6-7-95, 9-7-95, 8-31-95.

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1 is/are pending in the application.

~~Of the above~~, claim(s) 2-47 is/are ~~withdrawn from consideration~~ canceled.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of Reference Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, ~~Paper No(s)~~: 8 sheets

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

-- SEE OFFICE ACTION ON THE FOLLOWING PAGES --

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★ U.S. GPO: 1996-410-238/40050

If applicant desires priority under 35 U.S.C. § 120 based upon a parent application, specific reference to the parent application must be made in the instant application. It is noted that this appears as the first sentence of the specification following the title. Status of the parent application (whether patented or abandoned) should also be included. If a parent application has become a patent, the expression "Patent No." should follow the filing date of the parent application. If a parent application has become abandoned, the expression "abandoned" should follow the filing date of the parent application.

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. The title lacks specificity to retinoblastoma gene methods and thus is overly broad.

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The specification is objected to under 35 U.S.C. § 112, first paragraph, as failing to adequately teach how to make and/or use the invention, i.e. failing to provide an enabling disclosure.

On pages 137-147 of the specification there is described the detection of chromosome 3/17 aberrations. This is the only disclosure in the specification directed at these chromosomes. The cell lines studied are listed on page 141, first paragraph. None of those cell lines nor the accompanying discussion involve the retinoblastoma gene as claimed in claim 1, for example. Thus

there is a lack of instant enablement that a chromosome 3/17 rearrangement is associated with the retinoblastoma gene as claimed in claim 1.

Claim 1 is rejected under 35 U.S.C. § 112, first paragraph, for the reasons set forth in the above objection to the specification.

Claim 1 is rejected under 35 U.S.C. § 112, first paragraph, as the disclosure is enabling only for claims limited to retinoblastoma rearrangement detection wherein there is used the specific primers showing chromosomal rearrangements involving chromosomes 13 and 21 as given in Example IX starting on page 130 of the specification. There is no guidance or enablement of involvement of other chromosomes or primers. There is especially no guidance as to what is meant as to the location of "the vicinity" given in claim 1, line 3. Additionally, the reference cited by applicants as Bowcock et al. has been enclosed in the previous office action and summarizes in the abstract that the linkage between the chromosome 13 RB gene and cancer is not clear and may be secondary or present in some tumors only be chance. Thus even the instantly discussed rearrangement is in question as to its enablement. See M.P.E.P. §§ 706.03(n) and 706.03(z).

Claim 1 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is vague and indefinite in that it is supposedly a

method claim but does not recite even a single positive method step.

Claim 1 is vague and indefinite in that it cites a nucleic acid sequence (e.g. claim 1, line 2) as if it was a composition. A "sequence" of a nucleic acid is a characteristic of said nucleic acid and not a composition in itself. Thus citing a sequence as a composition is confusing and unclear as to what is meant. Clarification is requested.

The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
>
> Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103.

Claim 1 is rejected under 35 U.S.C. § 103 as being unpatentable over Weissman et al.

The instant invention is directed to the use of high complexity probes for hybridization labeling of chromosomes to detect rearrangements that may be associated with retinoblastoma.

Weissman et al. disclose in columns 5-6, bridging paragraph, that the invention therein described detects chromosomal arrangements such as the spacing between genes including linkage that may be related to a disease. Probed regions are disclosed as 50 kb to 2000 kb in column 9, lines 14-32, which clearly qualifies as high complexity probes as instantly claimed. The coverage of the probed region is accomplished as depicted in Figure 5 (discussed in column 18, lines 32-62) and discussed as to probes prepared in the bridging paragraph between columns 18 and 19. Weissman et al. lacks the specific retinoblastoma rearrangement disclosure but is motivated to study such rearrangements as summarized in column 2, line 13, through column 4, line 5.

Thus, it would have been obvious to someone of ordinary skill in the art at the time of the instant invention to practice high complexity probes and their use in hybridization assay as instantly claimed because Weissman et al. disclose the method and the motivation to apply this to diseases suspected of being caused by genetic rearrangements such as retinoblastoma gene rearrangements that result in cancer.

The non-statutory double patenting rejection, whether of the

obvious-type or non-obvious-type, is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent. *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); *In re Van Ornam*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); and *In re Goodman*, 29 USPQ2d 2010 (Fed. Cir. 1993).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321 (b) and (c) may be used to overcome an actual or provisional rejection based on a non-statutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.78 (d).

Effective January 1, 1994, a registered attorney or agent of record may sign a Terminal Disclaimer. A Terminal Disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim 1 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 2-20 of copending application Serial No. 08/487,701. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the copending application depend from the same claim 1 as the instant claim 1 and are clearly therefore species within instant claim 1.

This is a *provisional* obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means

an invention drawn to identical subject matter. *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claim 1 is provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of each claim 1 of copending applications Serial Nos. 08/487,701 and 08/478,387. This is a *provisional* double patenting rejection since the conflicting claims have not in fact been patented.

The disclosure is objected to because of the following informalities:

On page 18, the citation to Waldman et al. is incomplete.

On pages 131, 140, 144 and 145; lines 2, 11, 25, and 11; respectively; the citations are incomplete.

Appropriate correction is required.

No claim is allowed.

Papers related to this application may be submitted to Group 1800 by facsimile transmission. Papers should be faxed to Group 1800 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CFR § 1.6(d)). The CM1 Fax Center number is either (703) 305-7401 or (703) 305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ardin Marschel, Ph.D., whose telephone number is (703) 308-3894. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached on (703) 308-1152.

Any inquiry of a general nature or relating to the status of this application should be directed to the Chemical Matrix receptionist whose telephone number is (703) 308-0196.

September 3, 1996

Ardin H. Marschel

ARDIN H. MARSCHEL
PATENT EXAMINER
GROUP 1800